

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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CHARLES SEIFE,

Plaintiff,

-v-

No. 15 CV 5487-LTS

UNITED STATES FOOD AND DRUG  
ADMINISTRATION,

Defendant.

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MEMORANDUM OPINION AND ORDER

Plaintiff Charles Seife (“Plaintiff”), brings this action for declaratory and injunctive relief under 5 U.S.C. section 552, the Freedom of Information Act (“FOIA”) to obtain documents relating to news embargoes employed by Defendant United States Food and Drug Administration (“Defendant” or the “FDA”) between January 2010 and May 2014. (Docket entry no. 6 (“Complaint”); docket entry no. 68 (“Kotler Decl.”), at ¶ 13.) The FDA moved for summary judgment (docket entry no. 66), and Plaintiff cross-moved for summary judgment. (Docket entry no. 73.) The Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. section 1331, 5 U.S.C. section 552, and 28 U.S.C. section 2201.

The Court has considered the submissions of both parties carefully and, for the following reasons, denies Defendant’s motion for summary judgment as to the documents listed at entries 64-68 and 105 of the Vaughn index<sup>1</sup> and grants Defendant’s motion in all other

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<sup>1</sup> A Vaughn index is “a list of documents, identified by number, title and description, that a Government agency determines are responsive to a FOIA request” and “states the one or more FOIA exemptions that the agency claims justify withholding each document.” Am.

respects. Plaintiff's cross-motion for summary judgment is granted as to the documents listed at entries 64-68 and 105 of the Vaughn index and is denied in all other respects.

### **BACKGROUND**

The following facts are undisputed unless otherwise noted.<sup>2</sup> On May 5, 2014, Plaintiff submitted a FOIA request ("the Request") to the FDA, seeking:

Any e-mails, memoranda, presentations, or other documents dated from January 1, 2010 to the present, that discuss FDA's (or HHS') formal or informal policy (or policies) regarding news embargoes.

Any e-mails, memoranda, presentations, or other documents dated from January 1, 2010 to the present, discussing any restrictions imposed upon any member (or members) of the press in return for advance notice of (or a copy of) an FDA (or HHS) decision, policy or other documents(s).

Any e-mails, memoranda, presentations, or other documents dated from January 1, 2010 to the present, discussing any restrictions imposed upon any member (or members) of the press in return for the right to attend an FDA (or HHS) briefing, press conference, or teleconference.

Any e-mails, memoranda, presentations, or other documents dated from January 1, 2010 to the present, discussing or listing which journalists and/or media outlets will (or will not) be allowed to receive advance notice of and/or a copy of an FDA (or HHS) decision, policy, or other documents(s).

Any e-mails, memoranda, presentations, or other documents dated from January 1, 2010 to the present, discussing or listing which journalists and/or media outlets will (or will not) be allowed to attend a restricted briefing, press conference, or teleconference.

Any e-mails, memoranda, presentations, or other documents dated from January 1, 2010 to the present, between FDA (and/or HHS)

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Civ. Liberties Union v. Dep't of Justice, 844 F.3d 126, 129 (2d Cir. 2016) (explaining that the "term derives" from Vaughn v. Rosen, 484 F.2d 820, 821 (D.C. Cir. 1973)).

<sup>2</sup> Facts recited as undisputed are drawn from evidence as to which there is no nonconclusory contrary factual proffer.

and reporters (and/or news media outlets and/or press organizations) regarding FDA's embargo policy.

Any list of reporters, media organizations, and or representatives of the news media who have agreed to restrictions upon whom they might contact in pursuit of a story.

(Kotler Decl., Ex. A.) The FDA's Division of Freedom of Information ("DFOI") assigned the Request to the Office of Media Affairs ("OMA") – an office within the FDA's Office of External Affairs ("OEA") – because the Request sought records produced or exchanged by OMA staff. (Id. at ¶ 16.) Between March and August 2015, the DFOI produced 526 pages of records to Plaintiff in response to the Request. (Id. at ¶ 17.)

Plaintiff filed this lawsuit on July 15, 2015, asserting claims under the FOIA, the Administrative Procedures Act, and the Declaratory Judgment Act. (Complaint.) On October 30, 2015, this Court entered the parties' stipulation, which narrowed the Request to the following records:

any final FDA news embargo policy in place from January 1, 2010, to July 1, 2015;

any communications to or from OEA dated from January 1, 2010, to July 1, 2015, discussing (a) any changes to the news embargo policy, including those that relate to whether OEA can or should limit members of the press from sharing embargoed materials with third parties, (b) any instances in which OEA has limited members of the press from sharing embargoed material with third parties, (c) any deviation from an existing news embargo policy, whether it be on a one-time or permanent basis, (d) any news embargo related to FDA's January 19, 2011, announcement of the agency's action plan for improving the premarket notification process under section 510(k) of the [Federal] Food, Drug, and Cosmetic Act, or (e) any news embargo related to FDA's April 24, 2014, announcement regarding a proposed tobacco rule that would extend the agency's tobacco authority to cover additional tobacco products; and

any list of reporters, media organizations, and/or representatives of the news media who have agreed to restrictions upon whom they might contact in pursuit of a story, including those who agreed to any news embargo conditions for FDA's January 19, 2011, and

April 24, 2014, announcements, to the extent FDA has not produced such lists.

(Docket entry no. 16.) Thereafter, between November 6, 2015, and November 6, 2017, FDA produced approximately 7,450 pages of responsive documents to Plaintiff. (Kotler Decl., at ¶ 22.) On April 4, 2019, Plaintiff provided the FDA with a list of withheld or redacted records that Plaintiff sought to challenge. (Id. at ¶ 26.) After subsequent review and production by the FDA, the parties dispute whether the 119<sup>3</sup> records listed in the FDA's Vaughn Index (id., Ex. F) were properly redacted or withheld in their entirety from disclosure under FOIA Exemption 5, 5 U.S.C. § 552(b)(5) (hereinafter "Exemption 5"), which exempts from disclosure "inter-agency or intra-agency memorandums or letters [that] would not be available by law to a party other than an agency in litigation with the agency." (Id. at ¶ 29 (quoting 5 U.S.C. § 552(b)(5).) The FDA claims the redacted or withheld records are protected from disclosure by the Deliberative Process Privilege ("the Privilege.") (Docket entry no. 67, at 2.)

The records listed in the Vaughn Index are documents produced by or exchanged between OMA staff which relate to three OMA policy announcement events, and to one letter sent by the FDA to the editor of the New York Times. (Kotler Decl., at ¶ 31.) The first event was the August 4, 2010, announcement of the release of the FDA's Center for Devices and Radiological Health ("CDRH") Task Force recommendations relating to CDRH regulatory decision making. (Id. at ¶ 31(a).) The second event was the February 4, 2014, launch of the FDA's "Real Cost Campaign," a marketing campaign aimed at preventing tobacco use by at-risk

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<sup>3</sup> After the parties stipulated to narrow the scope of Plaintiff's FOIA request (docket entry no. 16), and after production of the records described in the Vaughn Index (see supra n.1), entry 119 on that index was found upon further review by FDA to fall outside of the parties' narrowing stipulation. (Docket entry no. 67, at 3, n.4.) Plaintiff agrees with the FDA's conclusion in that regard. Accordingly, the Court's decision does not address entry 119.

youth. (Id. at ¶ 31(b).) The third event was the April 24, 2014, announcement of the FDA’s proposed “Tobacco Deeming Rule,” which proposed extending the FDA’s regulatory authority to include all tobacco products. (Id. at ¶ 31(c).) The letter to the editor was submitted on May 6, 2014, in response to a May 4, 2014, New York Times article that concerned the proposed Tobacco Deeming Rule. (Id. at ¶¶ 31(d), 35.) The records FDA withheld include draft scripts and draft key messages for press interactions, draft anticipated questions and proposed answers for the announcement events, draft communications plans, a strategy memorandum, and email discussions about these four events. (Id. at ¶ 36.)

In declarations proffered by the FDA in support of its summary judgment motion, FDA officials explain that the OMA works collaboratively with substantive policymaking personnel of the FDA in developing communications strategies, including during the development of substantive policy decisions. Heidi Rebello, the Acting Director, Management and Strategic Initiatives, Office of the Chief of Staff, Office of the Commissioner of the FDA, offers testimony that OMA “plays a key role in the overall development and implementation of agency public health policies and objectives by, among other things, advising the agency regarding how to effectively communicate with the public” and that “FDA officials regularly involve OMA staff early during the regulatory decision making process, public health education campaign development, emerging health hazard responses, and other mission-critical activities to provide recommendations and insight regarding public communications that further FDA’s overall mission of protecting the public health.” (Docket entry no. 78 (“Rebello Decl.”), at ¶¶ 1, 4, 6.) According to Rebello, delay in involving OMA until after finalization of substantive policy measures would severely hamper the FDA’s public health mission by delaying the publication of proposed and final rules, information regarding recalls and safety, and information

regarding public health hazards. (*Id.* at ¶ 8.) Rebello proffers that FDA officials “included OMA staff in policy decisions regarding the drafting and public announcement of the Proposed Tobacco Deeming Rule” and that OMA “planned and oversaw the entire communication strategy for the publication” of that Proposed Rule, contributing to the successful elicitation of over 135,000 comments in response to the notice, which in turn helped the FDA to develop its final rule. (*Id.* at ¶ 9.) OMA staff were, according to Rebello, similarly involved in “policy decisions regarding the content and launch of the Real Cost tobacco use prevention campaign for young people,” and OMA’s decisions regarding the planning and coordination of the communication strategy for the campaign “contributed to FDA’s success in fulfilling its public health mission to reduce tobacco use, including by preventing approximately 350,000 U.S. youths aged 11–18 years from initiating smoking during 2014–2016.” (*Id.* at ¶ 10 (citation omitted).) Rebello also represents that OMA staff were involved in policy decisions regarding the public announcement of the CRDH’s preliminary report and task force recommendations, making communications decisions that contributed to the receipt of meaningful public comment that allowed the FDA later to revise and finalize recommendations in a way that better fulfilled the FDA’s public health mission. (*Id.* at ¶ 11.) As to involvement in the New York Times op-ed piece regarding allegedly inaccurate reporting of a proposed rule, Rebello states that OMA staff “regularly review and propose responses for agency officials regarding inaccurate news articles and publications reporting on proposed FDA policy” to ensure accurate information in aid of useful public comment and maintenance of the public’s trust. (*Id.* at ¶ 13.) Decisions regarding the use of press embargoes are made, according to Rebello, as part of “communications planning efforts,” on a case-by-case basis through consideration of a number of factors. (*Id.* at ¶¶ 16, 18.)

Sarah Kotler, the Director of the DFOI, proffers that, in responding to Plaintiff's FOIA requests,

DFOI personnel conducted a careful page-by-page, line-by-line review of all potentially responsive records collected by OMA and redacted information exempt from disclosure pursuant to FOIA. For all responsive records containing information exempt from disclosure, DFOI ensured that any reasonably segregable non-exempt information within these records was disclosed.

(Kotler Decl., at ¶ 25.)

Kotler represents that the information the FDA has withheld under claim of exemption from disclosure pursuant to Exemption 5 “reflects the internal exchange of advice, suggestions, opinions, analysis, ideas, and recommendations that occurred among government officials who were formulating messaging strategies for public engagement prior to” the four FDA events described above, which Kotler characterizes as “significant FDA policy events.” (*Id.* at ¶ 30.) Citing Department of Health & Human Services guidelines, Kotler explains that “[b]ecause FDA issues can be ‘technical, complex and difficult to translate into plain language,’ the [FDA] may, on occasion, announce such issues, on an embargoed basis, to give reporters extra time to understand and write about them prior to the information’s public release.” (*Id.* at ¶ 15 (citing U.S. Dep’t of Health & Hum. Servs., Guidelines on the Provision of Information to the News Media (2017))). Kotler proffers that “[t]he practice of providing embargoed news announcements and background materials, as well as access to subject matter experts, in advance of an announcement can assist the news media in understanding the substance and importance of the announcement and provide sufficient time to read the information and get necessary clarifications from the Agency prior to press time.” (*Id.* at ¶ 15.)

Kotler proffers that the records relating to the Task Force Reports are “directly relate[d] to FDA’s public health mission” with respect to ensuring “the safety and efficacy of

medical devices intended for human use.” (Id. at ¶ 32 (citation omitted).) According to Kotler, OMA developed the announcement policy event to announce the public release of the reports and solicit public comments on the preliminary recommendations therein, and “OMA’s deliberations regarding messaging decisions for the public release of the Task Force Reports are central to the FDA’s mission of protecting the public health” because the announcement was designed to “increase the public’s awareness and understanding of the Task Force Reports and to encourage meaningful public comments” and thereby enhance the FDA’s ability to carry out its safety and efficacy mission. (Id.) The FDA issued a Plan of Action, including draft guidance and proposing new regulation, following its review of comments. (Id.)

Kotler similarly proffers that the records associated with the Real Cost Campaign are directly related to the FDA’s tobacco-use reduction public health mission and that OMA developed “integrated, far-reaching and evidence-based public education campaigns related to prevention of youth tobacco use, including the Real Cost Campaign.” (Id. at ¶ 33.) The campaign was previewed to reporters on February 3, 2014, and officially launched on February 4, 2014. The withheld records, with the exception of one from February 3, 2014, relating to a press embargo and draft press release, are from January 2014. (Id.) Kotler represents that OMA engaged in deliberations regarding appropriate speakers and press invitees and that such deliberations were essential to the FDA’s mission because “successful messaging is essential for successful campaigns aimed at decreasing youth tobacco use.” (Id.)

As to the records relating to the Tobacco Deeming Rule, Kotler states that OMA developed the April 24, 2014, announcement of the rule to “publicize its release and to solicit public comments” and that the withheld materials, with two exceptions, predate April 23, 2014. (Id. at ¶ 34.) The April 23, 2014, document is an email containing “internal OMA deliberations

regarding how to respond to alleged ‘leaks’ regarding the proposed announcement prior to the official announcement on April 24, 2014.” (Id.) Reduction of the impact of a leak would, according to Kotler, “contribute to the successful announcement of the proposed rule.” (Id.) A second, April 24, 2014, document, is an email “contain[ing] internal OMA deliberations regarding how to respond to” a New York Times article of that same date “characterizing the proposed rule announcement.” (Id.) Kotler represents that the OMA deliberations regarding “messaging decisions for the proposed rule announcement” were mission-central for the FDA, in that the announcement was “designed to increase public awareness and understanding of the proposed rule and encourage meaningful public comment on the proposed rule.” (Id.) “[A]ccurate media representation” of the announcements and the public interest they generate affects “the quality of the Agency’s final regulation,” according to Kotler. (Id.) The Tobacco Deeming Rule was not finalized until two years after the announcement. (Id.)

The records associated with the May 4, 2014, New York Times article also relate to the public health mission, Kotler proffers. Kotler explains that the FDA “considered whether it should respond to the article to correct the article’s explanation of how the proposed rule would affect FDA’s regulatory authority,” and characterizes the messaging-related deliberations as central to the FDA’s public health mission, asserting that “inaccurate information about the scope of the proposed Tobacco Deeming Rule and FDA’s authority over tobacco products could affect public awareness and meaningful public comment on the announced proposed rule,” undermining the FDA’s regulatory authority expansion goal. (Id. at ¶ 35.)

Kotler further explains that the withheld draft scripts and draft key messages were prepared by lower-level OMA staff for senior agency officials’ preparation and use during policy events, reflecting the lower-level staffers’ analysis and judgment. (Id. at ¶ 37.) According to

Kotler, the records are often based on drafts of the substantive policies and are subject to change by senior officials prior to use. (Id.) Anticipated questions and proposed answers are also drafted by lower-level staff for more senior officials' use and reflect the analysis and judgment of the lower-level staff; the materials could be revised or "jettisoned or substantially revised for a variety of reasons, including if the policy to be announced is revised prior to release." (Id. at ¶ 38.)

Draft communications plans, according to Kotler, are prepared by lower-level staffers months ahead of proposed announcement dates and are revised in connection with ongoing discussions. She states:

The draft plans, as revised over time, reflect the drafters' evolving analysis and judgment regarding the objectives of the policy to be announced (which are often themselves being revised leading up to their announcement), various proposed media options for the announcement, and whether those options will meet the agency's proposed objectives, including whether and when it should use press embargoes (providing background information to journalists in advance of a press announcement), whether and when to work with other government branches, whether and when to work with regulated industry, as well as analysis regarding the proposed timing, attendees, speakers, and topics at such events. The plans also reflect ongoing internal discussions regarding the risks and benefits of various proposed options, including the impact that proposed timing, possible press invitees, possible speakers, and possible topics would have on the success of the policy event. Correct decisions on these issues are vital to a successful announcement. They do not reflect final Agency decisions.

(Id. at ¶ 39.) Kotler describes the strategy memorandum listed on the Index as having been "drafted by lower-level OMA staff to provide structure for internal ongoing discussions about developing issues among higher-level agency officials regarding the announcement of the proposed Tobacco Deeming Rule." (Id. at ¶ 40.) She continues:

This memorandum contains preliminary discussions that were later included in draft key messages and draft communications plans about that event—the final versions of which were produced to Plaintiff. It reflects the drafter's analysis and judgment regarding the risks and benefits of various media options, including whether and when to use press

embargoes, appropriate press to invite for accurate coverage, and appropriate timing of the announcement to ensure maximum impact. It also reflects the drafter's analysis of concerns and vulnerabilities regarding the draft substantive policy. The memorandum was used to facilitate further internal agency discussions and does not reflect a final agency decision.

(Id. at ¶ 40.)

The redacted emails, according to Kotler, reflect internal FDA communications about proposed revisions to the other types of documents, “including discussions regarding proposed changes to the underlying draft policies being announced and how those changes may affect the proposed policy events.” (Id. at ¶ 41.) The emails also, Kotler states, “contain internal agency communications about the risks and benefits of various proposed media options for these events including the impact that timing, possible press invitees, possible speakers, and topics for these events would have on the policy event.” (Id.)

Kotler represents that all of the withheld material is predecisional as to finalization of messaging decisions and/or finalization of the underlying policies being announced. (Id. at ¶ 42.) She further asserts that disclosure of discussions regarding such internal discussions of policy and decision formulation and related public outreach strategies “would chill the free flow of internal recommendations, candid assessments and other necessary exchanges in which government officials are involved” as well as “hamper” responsible officials’ ability “to formulate and carry out important FDA programs and their associated public announcements.” (Id. at ¶ 43.) She further cites risks of public confusion as to final FDA decisions on messaging and the underlying policies. (Id.)

Plaintiff Seife, a journalist, journalism professor and author, proffers a declaration in which he alleges that the FDA violated its own written policy when it utilized news embargoes. (Docket entry no. 74-1 (“Seife Decl.”), at ¶ 5.) Seife claims no personal knowledge

of the deliberative activities described in the FDA's declarations but lays out a conceptual legal and factual structure that he argues precludes protection of the withheld material, pursuant to Exemption 5 of the FOIA, as material reflecting government agency deliberative processes.

According to Plaintiff, the documents that he has requested potentially implicate three types of "policies," and deliberations as to only two of them are potentially eligible for Exemption 5 protection. (*Id.* at ¶ 9.) Seife proffers that "FDA's media policy" consists of "official FDA rules and guidelines about how the agency interacts with the media." (*Id.*) Citing June 2011 as the date on which the relevant policy was promulgated and proffering that the policy was "unaltered throughout the time period [covered by his FOIA] request," Seife asserts that none of the documents that are at issue here could involve the formulation of the press embargo policy that he claims was in effect. (*Id.* at ¶¶ 9-10.) The "FDA's substantive regulatory policies" are, according to Seife, "official FDA rules and guidelines about how the agency performs its regulatory duties such as regulating tobacco products and ensuring the safety and effectiveness of medications." (*Id.* at ¶ 9.) Seife places "press officers[']" function of "'messaging' ('spinning') to the public" substantive regulatory policies outside of the categories of policy making that are potentially protected by Exemption 5. (*Id.* at ¶ 11.) Although he acknowledges that "media officers typically begin working on media strategy before the [substantive] rule is promulgated," he asserts that "the media officers' back-and-forth have to do with deciding on that media strategy – the messaging of the rule – rather than contributing to decisions about the underlying substantive rule or policy itself." (*Id.*) Thus, he asserts that interactions in which FDA media personnel are involved "are not part of the substantive policy development itself" (*see id.*), and therefore cannot properly be withheld. Seife asserts that the FDA's position in this litigation seeks to "make it seem that media messaging strategies are in fact substantive policy

decisions,” and argues that information relating to the formulation and announcement of messaging strategies or marketing campaigns relating to substantive policy decisions is not protected. (*Id.* at ¶ 12.) For example, Seife offers the following commentary on the FDA’s position regarding the withholding of a communications strategy memorandum regarding the “deeming rule”:

The strategy memo’s purported discussion of ‘risks and benefits of various media options, including whether and when to use press embargoes, appropriate press to invite for accurate coverage, and appropriate timing of the announcement to ensure maximum impact . . . are not covered by the [deliberative process privilege<sup>4</sup>] because they don’t involve deliberations [about] a substantive policy decision (they’re about media strategy, not about the underlying substantive decision – the new rule itself’ . . . They are deliberative only to messaging. . . . The messaging persons are not part . . . of the team deliberating about the decision in flux – but are mere observers commenting on how to present . . . decisions being made by others.

(*Id.* at ¶ 19.)

As noted above, Seife contends that FDA’s use of news embargoes in connection with the 2014 events violated a policy adopted by the FDA in June 2011; the target of his FOIA request is this alleged “wrongdoing by executive branch officials.” (*Id.* at ¶¶ 22, 23, 24.)

“Without being able to see the draft versions [of key messages, communications plans, questions and answers, etc.] and comparing them to the final versions,” Seife explains, “Plaintiff will be unable to analyze precisely when, how, and why FDA changed its plans to spin FDA decisions to allow for the use of the (nominally forbidden) close-hold embargo, or do a similar analysis of other ‘messaging’ concerns that form the core purpose of the office that produced the responsive documents.” (*Id.* at ¶ 26.) He thus specifically seeks information regarding the messaging strategy deliberations that the FDA has invoked Exemption 5 to protect.

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<sup>4</sup> See discussion *infra* page 15.

The parties filed cross-motions for summary judgment. (Docket entry nos. 66 and 73.) As explained below, the Court finds that the FDA's submissions are sufficient to permit a determination that all of the information it has withheld under Exemption 5, with the exception of information corresponding to Vaughn index entries 64-68 and 105, is exempt from disclosure.

## **DISCUSSION**

### **Rule 56 Summary Judgment Standard**

Rule 56(a) of the Federal Rules of Civil Procedure provides that summary judgment is to be granted in favor of a moving party where that party can demonstrate “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed R. Civ. P. 56(a). Material facts are those that “might affect the outcome of the suit under the governing law,” and there is a genuine dispute where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Rojas v. Roman Catholic Diocese of Rochester, 660 F.3d 98, 104 (2d Cir. 2011) (internal quotation and citation omitted). In evaluating a motion for summary judgment, the Court must “construe all evidence in the light most favorable to the nonmoving party, drawing all inferences and resolving all ambiguities in its favor.” Dickerson v. Napolitano, 604 F.3d 732, 740 (2d Cir. 2010) (citation omitted).

It is the agency's burden to demonstrate that withheld information falls within a FOIA exemption. See Carney v. U.S. Dep't of Justice, 19 F.3d 807, 812 (2d Cir. 1994) (citing 5 U.S.C. § 552(a)(4)(B)). “[T]he general rule in this Circuit is that in FOIA actions, agency affidavits alone will support a grant of summary judgment.” Ferguson v. FBI, No. 89-CIV-5071, 1995 WL 329307, at \*2 (S.D.N.Y. June 1, 1995), aff'd, 83 F.3d 41 (2d Cir. 1996) (citing Carney, 19 F.3d at 812). “Summary judgment is warranted on the basis of agency affidavits when the

affidavits describe the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor by evidence of agency bad faith.” Wilner v. Nat’l Sec. Agency, 592 F.3d 60, 73 (2d Cir. 2009) (quotation omitted). Courts accord agency affidavits a presumption of good faith. See Carney, 19 F.3d at 812.

### FOIA Exemption 5

The FOIA was enacted to “assure the availability of Government information necessary to an informed electorate.” H.R. Rep. No. 89-1497, 1966 WL 4304, at 2429. The FOIA struck a “workable balance between the right of the public to know and the need of the Government to keep information in confidence to the extent necessary without permitting indiscriminate secrecy.” Id. at 2423. Accordingly, the FOIA “mandates disclosure of records held by a federal agency unless the documents fall within enumerated exemptions.” Dep’t of the Interior v. Klamath Water Users Protective Ass’n, 532 U.S. 1, 7 (2001) (internal citation omitted). The Supreme Court has repeatedly stated that these exemptions must be interpreted narrowly to accomplish the FOIA’s goal of broad disclosure. Id. at 8. Upon complaint, the Court must determine de novo whether the agency’s claimed exemption applies. Wilner, 592 F.3d at 69.

The FDA argues that FOIA Exemption 5 applies to protect the records described in the Vaughn Index from disclosure under FOIA. (Docket entry no. 67; Kotler Decl., Ex. F.) Exemption 5 exempts from disclosure “inter-agency or intra-agency memorandums or letters [that] would not be available by law to a party other than an agency in litigation with the agency.” Klamath, 532 U.S. at 2 (quoting 5 U.S.C. § 552(b)(5)). “Stated simply, agency

documents which would not be obtainable by a private litigant in an action against the agency under normal discovery rules (e.g., attorney-client, work-product, executive privilege) are protected from disclosure under Exemption 5.” Tigue v. U.S. Dep’t of Justice, 312 F.3d 70, 76 (2d Cir. 2002) (quoting Grand Cent. P’ship v. Cuomo, 166 F.3d 473, 481 (2d Cir. 1999)). The Government here relies upon the Deliberative Process Privilege (the “Privilege”), which is “encompassed within the executive privilege,” Grand Cent. P’ship, 166 F.3d at 481, and protects the “decision making processes of government agencies . . . [by exempting from disclosure] documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.” N.L.R.B. v. Sears, Roebuck & Co., 421 U.S. 132, 150 (1975) (internal quotations and citations omitted). The rationale animating the Privilege is “the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance ‘the quality of agency decisions,’ by protecting open and frank discussion among those who make them within the Government.” Tigue, 312 F.3d at 76 (quoting Klamath, 532 U.S. at 8). The Privilege applies only to documents that are both (1) “predecisional” and (2) “deliberative.”<sup>5</sup> Id.

A document is predecisional if it is “prepared in order to assist an agency decisionmaker in arriving at his decision.” Nat’l Council of La Raza v. Dep’t of Justice, 411 F.3d 350, 356 (2d Cir. 2005) (citation omitted). “In assessing whether a document is predecisional, courts also consider whether the government can: (i) pinpoint the specific agency

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<sup>5</sup> Exemption 5 also requires that the document be an inter-agency or intra-agency document. 5 U.S.C. § 552(b)(5). The record here demonstrates, and the parties do not dispute, that the documents at issue satisfy this requirement. (See docket entry no. 58 (agreeing that the dispute is limited to “certain communications within the FDA’s Office of External Affairs”).)

decision to which the document correlates, (ii) establish that its author prepared the document for the purpose of assisting the agency official charged with making the agency decision, and (iii) verify that the document precedes, in temporal sequence, the decision to which it relates.” Adelante Ala. Worker Ctr. v. U.S. Dep’t of Homeland Sec., 376 F. Supp. 3d 345, 357 (S.D.N.Y. 2019) (citation omitted). While an agency need not demonstrate that an actual decision resulted from the document for which the privilege is claimed, the agency must demonstrate that the document “related to a specific decision facing the agency.” Tigue, 312 F.3d at 80. Accordingly, documents that are “merely part of a routine and ongoing process of agency self-evaluation” are not predecisional. Id. (quoting Maricopia Audubon Soc. v. U.S. Forest Serv., 108 F.3d 1089, 1094 (9th Cir. 1997).)

A document is deliberative if it is “actually . . . related to the process by which policies are formulated.” Grand Cent. P’ship, 166 F.3d at 482 (quotation omitted); see also Tigue, 312 F.3d at 80 (the “record must bear on the formulation or exercise of policy-oriented judgment”). Courts have looked to factors such as whether the document “(i) formed an essential link in a specified consultative process, (ii) ‘reflect[s] the personal opinions of the writer rather than the policy of the agency,’ and (iii) if released, would ‘inaccurately reflect or prematurely disclose the views of the agency.’” Grand Cent. P’ship, 166 F.3d at 482 (quoting Providence Journal Co. v. U.S. Dep’t of the Army, 981 F.2d 552, 559 (1st Cir. 1992)). The Privilege generally does not apply to factual material, Natural Res. Def. Council v. U.S. Env’tl. Prot. Agency, 954 F.3d 150, 157 (2d Cir. 2020), and any non-privileged material that is “reasonably segregable” from the deliberative portions of records must be produced. Tigue, 312 F.3d at 82 (citing 5 U.S.C. § 552(b)). Additionally, if non-deliberative or post-decisional material would reveal how predecisional deliberations progressed, that material is also

privileged. See Fox News Network, LLC v. U.S. Dep’t of The Treasury [“Fox News I”], 739 F. Supp. 2d 515, 545 (S.D.N.Y. 2010) (“Communications regarding how to present agency policies . . . are properly withheld if their release would reveal the status of internal deliberations and substantive policy matters.”); Citizens Union of City of New York v. Attorney General of New York, 269 F. Supp. 3d 124, 165 (S.D.N.Y. 2017) (“[A] draft public statement may be privileged if disclosure of the communications would reveal how the Legislature’s or Governor’s deliberations regarding the underlying ethics reform legislation progressed over time.”).

Here, the core of the parties’ dispute is whether documents that relate to the formulation of the FDA’s communications strategies and decisions in connection with public announcements of certain substantive policies are covered by the Privilege and therefore exempt from disclosure. (Docket entry no. 77, at 1; docket entry no. 83, at 1.) Courts have referred to such documents and the communications decisions to which they relate as “messaging” documents and decisions, and this Court will do the same here. The key issue in this case is whether messaging decisions are among the kinds of agency decisions that Exemption 5 was meant to enhance through confidential deliberation. Plaintiff argues that messaging decisions (which he also refers to as “spinning”) generally are not protected by the Deliberative Process Privilege unless the messaging decision would reveal deliberations about another substantive policy decision facing the agency. (Docket entry no. 74, at 11.) Defendant, on the other hand, argues that messaging records may fall within the Deliberative Process Privilege “regardless of whether they also reflect deliberations regarding substantive agency policy” because messaging discussions “can be just as deliberative as other agency decision-making.” (Docket entry no. 67, at 7-8.) For example, an agency’s “decision of how, and to what extent, to convey [a] policy to the public may require input by many working components within the agency” and may involve

“the evaluation of alternative public relations policies, policies which by their very nature are audience-sensitive and must anticipate public reaction.” (*Id.* at 8 (quoting Seife v. U.S. Dep’t of State (“Seife I”), 298 F. Supp. 3d 592, 616 (S.D.N.Y. 2018)).)

The parties agree that the Second Circuit has not directly addressed whether messaging decisions are eligible for protection under the Deliberative Process Privilege,<sup>6</sup> see National Day Laborer Organizing Network v. U.S. Customs and Immigration, 486 F. Supp. 3d 669, 700 (S.D.N.Y. 2020), and courts in this District remain split over the scope of the Privilege. See Seife I, 298 F. Supp. 3d at 614-15 (collecting cases); New York v. Dep’t of Com., No. 18-cv-2921, 2018 WL 4853891, at \*1 (S.D.N.Y. Oct. 5, 2018) (same). Historically, courts within this District have taken the approach endorsed by Plaintiff, finding that “communications concerning how to present agency policies to the press or public . . . typically do not qualify as substantive policy decisions protected by the deliberative process privilege,” and those records

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<sup>6</sup> The Seife I decision from this District cites American Civil Liberties Union v. U.S. Dep’t of Justice, 844 F.3d 126 (2d Cir. 2016) for the proposition that the Second Circuit has “previewed” its position on messaging decisions. 298 F. Supp. 3d at 616. In ACLU v. U.S. Dep’t of Justice, the Second Circuit held that Exemption 5 permitted the DOJ to withhold a “draft of a proposed op-ed article that suggested some ways of explaining the Government’s legal reasoning in support of drone strikes.” Seife I, 844 F.3d at 616. The Seife court held that, because the draft was not described as containing deliberations connected to the underlying drone strike policy, but was rather “in connection with the ways in which the administration’s justification for those strikes would be presented to the public,” the Second Circuit must have viewed messaging decisions as the kind of decision Exemption 5 was meant to protect. *Id.* Subsequent decisions within this District have declined to read ACLU v. U.S. Dep’t of Justice as resolving the split within this District without substantive discussion. See, e.g., New York v. U.S. Dep’t of Com., No. 18-cv-2921, 2018 WL 4853891, at \*1, n.1 (S.D.N.Y. Oct. 5, 2018) (departing from Seife “given the Second Circuit’s lack of any real analysis of the issue”); Nat’l Day Laborer Org. Network v. U.S. Immigration & Customs Enf’t, 486 F. Supp. 3d 669, 700, n. 10 (S.D.N.Y. 2020) (same); Natural Res. Def. Council v. U.S. Envtl. Prot. Agency, No. 17-CV-5928, 2019 WL 6467497, at \*2 (declining reconsideration based on ACLU v. U.S. Dep’t of Justice decision). This Court does not interpret ACLU v. U.S. Dep’t of Justice as significantly indicative of the Second Circuit’s views on the applicability of Exemption 5 to messaging deliberations.

are only exempt from disclosure if they “would reveal the status of internal agency deliberations on substantive policy matters.” Fox News Network, LLC v. U.S. Dep’t of Treasury, 911 F. Supp. 2d 261, 266-277 (S.D.N.Y. 2012) (citing Fox News I, 739 F. Supp. 2d at 545); see also MacNamara v. City of New York, No. 04-CIV-9216, 2007 WL 1169204, at \*5 (S.D.N.Y. Apr. 20, 2007) (“Whether or not the Mayor should use . . . suggested ‘talking points’ is not the sort of public policy decision that falls within the scope of the [deliberative process] privilege.”).

However, in Seife I, a court in this District endorsed a broader application of the Privilege that is often employed by district courts in the District of Columbia, and which Defendant argues this Court should endorse here, finding that messaging decisions are eligible for protection under the Deliberative Process Privilege because “an agency’s decision regarding how to present its substantive policies to the public often involves the evaluation of alternative public relations policies, policies which . . . are audience-sensitive and must anticipate public reaction.” Seife I, 298 F. Supp. 3d at 616. The Seife I decision found that messaging decisions may be protected by the Privilege “[e]ven when an underlying decision or policy has already been established by the agency” because “the decision of how, and to what extent, to convey that policy to the public may require input by many working components within the agency, or even an analysis of the underlying policy itself.” Id.; see Sierra Club v. U.S. Dep’t of Interior, 384 F. Supp. 2d 1, 19 (D.D.C. 2004) (finding draft talking points protected by Deliberative Process Privilege because they were “predecisional to the actual communication of [the] information and issues”).

Recently, courts in this District have adopted an approach that “lies between these two positions.” Nat’l Day Laborer, 486 F. Supp. 3d at 701 (finding “against a rule either categorically exempting, or categorically protecting” messaging documents); see also Dep’t of Com., 2018 WL 4853891, at \*2 (same). These courts recognize that messaging decisions

“‘about what and how to communicate with Congress, the press, or the public can’— in some circumstances – ‘involve substantive policymaking (or at least substantive policy refinement) of the type that Congress has delegated to the agency, and the purposes of the privilege are served by protecting the deliberations leading to those decisions.’” Nat’l Day Laborer, 486 F. Supp. 3d at 701 (quoting Dep’t of Com., 2018 WL 4853891, at \*2). However, these courts have cautioned that accepting that “all deliberations over what to say are protected by the privilege” would go “too far,” as “that suggestion would render the privilege’s restriction to ‘predecisional’ deliberations a nullity because, [as] agencies are in constant communication with the public, the press, and Congress, all ‘messaging’ deliberations would be ‘predecisional’ with respect to some future messaging decision.” (Id. (quoting Dep’t of Com., 2018 WL 4853891, at \*2) (emphasis in original).) Thus, these courts have determined that where “‘communications are of a nature that they would reveal the deliberative process underlying a not-yet-finalized policy decision,’ or a not-yet-announced policy decision, deliberations about what message to deliver, and how to go about doing so, can fall within the protections” of the Privilege. (Id. (quoting Dep’t of Com., 2018 WL 4853891, at \*2).) However, where “‘messaging’ communications amount to little more than deliberations over how to spin a prior decision, or merely reflect an effort to ensure that an agency’s statement is consistent with [a] prior decision,” these courts found “protection would do little to advance the purposes” underlying the Privilege. Id. (quoting Dep’t of Com., 2018 WL 4853891, at \*2); see also id. (explaining that “what FOIA requesters are frequently seeking is evidence of discrepancies between what their government . . . is saying in public versus what it is saying behind closed doors” and that “is the type of concern that FOIA seeks to vindicate” (quotation omitted).)

This Court agrees that this inquiry appropriately balances the purpose underlying the Deliberative Process Privilege, to protect “the quality of agency decisions by preserving and encouraging candid discussion between officials,” see Nat’l Council of La Raza, 411 F. 3d at 356, with the “basic purpose of FOIA to ensure an informed citizenry.” See Nat’l Day Laborer, 486 F. Supp. 3d at 688 (internal quotation and citation omitted). Moreover, this approach’s recognition that messaging decisions reflecting deliberations about how best to communicate a not-yet-finalized or not-yet-announced policy decision can be protected provides an appropriate threshold question for analysis of the current dispute, particularly in light of the testimony proffered by the FDA that messaging communications are central to the agency’s public health mission of educating and informing the public about ongoing health concerns and the agency’s responses to those concerns. (See Kotler Decl., at ¶ 43 (explaining that disclosure would “chill the free flow of internal recommendations, and . . . would hamper the ability of responsible officials to formulate and carry out important FDA programs and their associated public announcements”); see id. at ¶ 32 (explaining that deliberations regarding messaging decisions are “central to FDA’s mission of protecting the public health,” as policy announcements are “designed to increase the public’s awareness and understanding . . . and to encourage meaningful public comments”); see id. at ¶ 33 (explaining that public educational campaigns are developed “[t]o advance FDA’s efforts to protect the public”); see Rebello Decl., at ¶ 6 (noting the early involvement of OMA staff during “the regulatory decisionmaking process, public health education campaign development, emerging health hazard responses, and other mission-critical activities . . . that further FDA’s overall mission of protecting the public health”); see id. at ¶ 7 (“Early OMA involvement in FDA decisionmaking is critical for ensuring fast, reliable, and

accurate public communication regarding public health concerns, including but not limited to, proposed rulemaking and guidances, . . . [and] public health campaigns.”.)

Thus, the Court will first consider whether the FDA has demonstrated that the documents it has withheld are ones that relate to messaging policy matters and concern not-yet-finalized or not-yet-announced policy decisions.

1. Documents Relating to August 4, 2010, Announcement of the Release of the CDRH Task Force’s Recommendations

The FDA proffers that the documents relating to the first policy event reflect OMA’s “deliberations regarding messaging decisions for the public release of the Task Force Reports” concerning preliminary recommendations for strengthening a premarket review process for medical devices. (Kotler Decl., at ¶ 32.) These records, identified in Entries 35-48 and 95 of the Vaughn index, were dated from July 20-July 30, 2010, and thus predated the announcement of the Task Force’s Recommendations. (Id.) The FDA has proffered testimony that the deliberations embodied in these documents were “central to [the] FDA’s mission of protecting the public health” because a “successful announcement of the[] preliminary recommendations was designed to increase the public’s awareness and understanding of the Task Force Reports and to encourage meaningful public comments, thereby enhancing FDA’s ability to ensure the safety and efficacy of medical devices.” (Id.) Because these documents would “reveal the deliberative process” regarding “what message to deliver, and how to go about doing so” in connection with a “not-yet-announced policy decision,” namely the Task Force’s Recommendations for improvement to the premarket review process for medical devices, the Court finds these documents are potentially eligible for protection under the Privilege. Nat’l Day Laborer, 486 F. Supp. 3d at 701 (internal quotation and citation omitted); cf. Natural Res. Def. Council v. U.S. Env’tl. Prot. Agency, No. 17-cv-5928, 2019 WL 4142725, at \*9 (S.D.N.Y. Aug.

30, 2019) (finding draft speech discussing final rule that had been published several days earlier was not privileged because the messaging document concerned the presentation of a previously-decided policy); Morales v. City of New York, No. 18-cv-1573, 2019 WL 6213059, at \*5 (S.D.N.Y. Nov. 21, 2019) (finding City had not met burden to show the Privilege applied to “emails regarding the City’s response to press inquiries about allegations of whistleblower retaliation against a former City employee” where employee had already been fired).

## 2. Documents Relating to February 4, 2014, Launch of Real Cost Campaign

The FDA has proffered testimony that the documents relating to the second policy event concern “messaging decisions for the launch” of the Real Cost Campaign, “including appropriate speakers and press invitees.” (Kotler Decl., at ¶ 33.) The documents, identified at entries 13-34 and 114-15, were generated in January 2014, with the exception of one February 3, 2014, email thread “discussing use of a press embargo and the draft press release for the launch” of the Campaign, and thus all pre-date the announcement of the Campaign to the public. (Id.) The FDA has proffered testimony that the deliberations reflected in these documents “were central to FDA’s mission of protecting the public health” because “successful messaging is essential for successful campaigns aimed at decreasing youth tobacco use.” (Id.) Because the FDA represents that disclosure of these documents would reveal the deliberative discussions regarding the messaging decisions for the launch of the Real Cost Campaign prior to the launch of that campaign, the Court finds that they are potentially eligible for protection under the Deliberative Process Privilege. See Dep’t of Com., 2018 WL 4853891, at \*2 (recognizing that an agency’s messaging decisions can be “bound up with an agency’s central policy mission” and explaining that “deliberations within the Federal Reserve about the timing and content of a policy announcement . . . relate to a future decision (what to say and when to say it) that

implicates questions within the scope of the agency’s delegated policymaking authority – and are therefore the type of deliberations the privilege is designed to protect”).

### 3. Documents Relating to April 24, 2014, Announcement of Proposed Tobacco Deeming Rule

The documents relating to the third policy event concern the April 24, 2014, announcement of the Proposed Tobacco Deeming Rule, which would extend the FDA’s regulatory authority under the Tobacco Control Act. (Kotler Decl., at ¶ 34). All but two of the documents relating to the announcement of the rule were developed between January 24, 2014, and April 22, 2014. (*Id.* (citing Vaughn index, entries 1-12, 49-63, 69-94, 96-103, 106-113, 116-118).) The FDA proffers that that subset of documents, created between January 24, 2014, and April 22, 2014, relates to the OMA’s development of the April 24, 2014, announcement of the proposed rule “to publicize its release and to solicit public comments” and reflects deliberations that were “central to the FDA’s mission of protecting the public health” because “a successful announcement . . . was designed to increase public awareness and understanding of the proposed rule and encourage meaningful public comment . . . further advancing the FDA’s goal of extending authority over tobacco products.” (*Id.*) On the basis of the FDA’s proffer, the Court finds that the subset of documents created between January 24, 2014, and April 22, 2014, may be protected by the Privilege.

Entry 104 of the Vaughn index reflects a document dated April 23, 2014, that the FDA proffers contains “internal OMA deliberations regarding how to respond to alleged ‘leaks’ regarding the proposed announcement prior to the official announcement on April 24, 2014.” (*Id.*) While this document was generated on the same day that the FDA briefed reporters regarding the proposed rule, it predates the official announcement of the proposed rule to the public, and the FDA proffers that it “contains internal OMA deliberations how to respond to

alleged ‘leaks’ regarding the proposed April 24, 2014 announcement,” reduction of which would contribute to the “successful announcement of the proposed rule.” (*Id.*) The Court finds that this document is potentially eligible for protection under the Privilege because it predates the decision at issue, the announcement of the rule to the public, and the FDA proffers that its disclosure would reveal agency deliberations regarding how to make that announcement successful.

Entry 105 of the Vaughn index arises in a different context. That entry corresponds to a document from April 24, 2014, that the FDA proffers consists of “OMA deliberations regarding how to respond to an April 24, 2014, New York Times article characterizing the proposed rule announcement.” (*Id.*; see also docket entry no. 67, at 11, n. 7.) The FDA proffers that its “efforts to ensure accurate reporting on the announcement of the proposed Tobacco Deeming Rule . . . furthers (sic) FDA’s overall goals because the quality of the Agency’s final regulation depends in part on the accurate media representation of those announcements, as well as the public interest they generate.” (Kotler Decl., at ¶ 34.) The FDA Commissioner issued a letter to the editor of the New York Times on May 6, 2014, in response to the paper’s reporting on the announcement. (*Id.* at ¶ 41.) The Court finds that this entry is not eligible for protection under the Deliberative Process Privilege. This messaging document reflects an effort to ensure that the newspaper’s reporting on the proposed rule and announcement was consistent with the information the agency had provided to the public on April 24, 2014, and thus concerned an already-completed messaging policy decision. Withholding “deliberations over how to spin a prior decision” or reflecting efforts to ensure a “statement is consistent with [a] prior decision” would not advance the purposes underlying the Privilege. Nat’l Day Laborer, 486 F. Supp. 3d at 701-702 (finding talking points not protected

under the Privilege were they were “in service of communicating . . . an existing policy decision to various stakeholders”); Dep’t of Com., 2018 WL 4853891, at 3 (finding draft responses to Washington Post not protected because they “merely reflect deliberations about what message should be delivered to the public about an already-decided policy decision” (internal quotation and citation omitted) (emphasis in original)). To the contrary, disclosure of documents seeking to promote consistency of third-party reporting with an already-issued agency announcement would potentially assist in decreasing public confusion. Accordingly, entry 105 must be produced.

4. Documents Relating to FDA’s Response to May 4, 2014, New York Times Article Regarding Proposed Tobacco Deeming Rule

The documents at issue in connection with event four relate to agency deliberations regarding whether and how to respond to a May 4, 2014, New York Times article regarding the proposed Tobacco Deeming Rule that was announced on April 24, 2014. (Kotler Decl., at ¶ 35 (citing Vaughn index entries 64-68).) The FDA proffers that the documents are dated the morning of May 4, 2014, and concern “how to respond to [the] article” including whether “to correct the article’s explanation of how the proposed rule would affect FDA’s regulatory authority.” (Id.) Because these documents reflect deliberations regarding the decision to communicate with the press about an already-announced proposed rule, the Court finds that entries 64-68 are not eligible for protection by the Privilege and must be produced. The Court notes that, to the extent the FDA argues that these documents should be treated as privileged because they predated the adoption of the final Tobacco Deeming Rule in May 2016 and “reflect nonfinal versions” of the rule, its effort is unavailing. The nonfinal version of the rule had already been disclosed to the public in the April 24, 2014, announcement. (Id. at ¶ 41; see also docket entry no. 67 at 11-12, n.7.) The FDA explicitly acknowledges that the May 2014 New

York Times article was “about the proposed Tobacco Deeming Rule as [the agency] was preparing to receive public comments on that rule.” (See docket entry no. 67 at 14 (citing Kotler Decl., at ¶ 35).) Deliberations regarding messaging decisions seeking to clarify an already-announced version of the rule fall outside of the scope of the Deliberative Process Privilege.

#### Predecisional and Deliberative Nature of the Withheld Material

Having established that the documents at issue, with the exception of those reflected at Vaughn index entries 64-68 and 105, are potentially eligible for protection under the Deliberative Process Privilege, it remains the FDA’s burden to demonstrate that each such document is predecisional and deliberative with regard to an identifiable decision facing the agency and therefore can properly be withheld. See Tigue, 312 F.3d at 80. The FDA must explain the “function and significance [of the document] in the agency’s decisionmaking process.” Seife I, 298 F. Supp. 3d at 617 (quotation omitted). If the FDA describes its “justifications for nondisclosure with reasonably specific detail, demonstrate[s] that the information withheld logically falls within the claimed exemption, and [is] not controverted by either contrary evidence in the record nor by evidence of agency bad faith,” the FDA is entitled to summary judgment. Wilner, 592 F.3d at 73 (quotation omitted).

Here, the FDA has proffered a Vaughn index with individual entries for documents withheld or redacted, the Kotler Declaration describing the types of documents withheld in connection with each event and their strategic significance, and the Rebello declaration describing the OMA’s role in FDA decision-making. Having examined carefully these documents the Court finds that the FDA has met its burden of establishing that the

remaining documents are predecisional and deliberative and therefore withheld properly pursuant to Exemption 5.

First, the FDA has met its burden of showing that the documents at issue are predecisional with respect to specific decisions facing the agency. The Kotler Declaration explains that “[t]he records detailed on the Vaughn index are internal OMA documents associated with the following policy events:” (1) “the August 4, 2010, announcement of the release of FDA’s . . . Task Force recommendations”; (2) the February 4, 2014, launch of FDA’s . . . marketing campaign aimed at preventing tobacco use in at-risk youth”; and (3) the “April 24, 2014, announcement of [the] proposed tobacco ‘deeming’ rule.” (Kotler Decl. at ¶ 31.) In its Vaughn index, the FDA indicates the date each individual document corresponding to entries 1-63, 69-104, and 106-118 of the index was created and connects it to one of these events at issue. Each of the documents, corresponding to these entries of the Vaughn index, predates the policy event to which it is related. Moreover, the Kotler declaration provides a factual overview of each one of the events at issue and an explanation of why the documents relating to each event were significant to achieving the agency’s desired outcome with respect to that particular event and also to the FDA’s overall mission. (*Id.* at ¶ 32 (explaining records associated with announcement of the Task Force Reports were “central to FDA’s mission of protecting the public health” and a “successful announcement . . . was designed to increase the public’s awareness and understanding of the Task Force Reports and to encourage meaningful public comments”); *id.* at ¶ 33 (explaining that “deliberations regarding messaging” were “essential for successful campaigns aimed at decreasing youth tobacco use”); *id.* at ¶ 34 (explaining that deliberations regarding proposed rule announcement “were central to FDA’s mission” to “increase public awareness and understanding . . . and encourage meaningful public comment”).)

Thus, the FDA has “(i) pinpoint[ed] the specific agency decision to which the document correlates, (ii) establish[ed] that its author prepared the document for the purpose of assisting the agency official charged with making the agency decision, and (iii) verif[ed] that the document precedes, in temporal sequence, the decision to which it relates.” Seife I, 298 F. Supp. at 614 (quotation and citation omitted).

Second, the FDA has met its burden of establishing that the documents at issue are deliberative. The Vaughn index entries and the Kotler declaration indicate that many of the documents are in draft form, including draft scripts, draft key messages for press interactions, draft anticipated questions and proposed answers, draft communications plans, and a draft strategy memorandum. (See Kotler Decl., at ¶ 36.) The Kotler declaration explains that these draft documents are created by lower-level OMA staff and therefore reflect the “drafters’ own analysis and judgment” throughout the consultative process, rather than the views of the agency. (Id. at ¶¶ 37-40; see Seife I, 298 F. Supp. 3d at 613 (explaining the privilege “protects ‘recommendations, draft documents . . . and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency’” (quoting Grand Cent. P’Ship, 166 F.3d at 482))). Moreover, the Kotler declaration proffers that these draft documents and the views discussed in them are subject to revision, and that “significant changes may be made to them prior to finalization[,]” depending “on review by high-level officials and the final version of the policy being announced.” (Kotler Decl., at ¶¶ 37-40.) The internal agency email messages, the Kotler declaration explains, include communications regarding “proposed revisions to the types of documents” discussed above including draft scripts, key messages, and anticipated questions and answers, and reflect “discussions regarding proposed changes to the

underlying draft policies being announced and how those changes may affect the proposed policy events[.]” (Id. at ¶ 41.)

The FDA has also provided sufficient information to demonstrate the documents’ role in the consultative process in preparing for the events at issue. The Kotler Declaration proffers that intra-agency emails included “communications about the risks and benefits of various proposed media options for these events, including the impact that timing, possible press invitees, possible speakers, and topics for these events have on the policy event.” (Id. at ¶ 41.) This is supplemented by the information provided in the Vaughn index, which demonstrates that emails were exchanged among individuals with different roles and at different levels of the agency during the decision-making process. (See docket entry no. 77, at 13 (“[T]he Vaughn Index provides the title of each author and recipient—including . . . a “message sent from a ‘Press Officer’ to the ‘Deputy Director’ of the Office of External Affairs (of which OMA is a part)” (citing Vaughn index, entry 3).) The FDA has proffered that the other types of documents at issue here, including draft communications plans, scripts, key messages, and anticipated questions and answers, reflected similar deliberations about the “risks and benefits” of various messaging strategies. (See Kotler Decl., at ¶¶ 37-40.) Moreover, through the Rebello Declaration, the FDA has provided an overview of the “key role” the OMA plays in the FDA’s overall policy-making process, explaining that OMA participates in the “overall development and implementation of agency public health policies and objectives by, among other things, advising the agency regarding how to effectively communicate with the public.” (Rebello Decl., at ¶ 4.)

Thus, the Court finds that the information proffered in both the Vaughn index and the Kotler and Rebello Declarations is sufficient to meet the FDA’s burden of establishing that

the documents eligible for protection under the Privilege are both predecisional and deliberative and thus are properly withheld pursuant to Exemption 5.

### Segregability

Under FOIA, the FDA must disclose any “reasonably segregable” information that is not inextricably intertwined with exempt information. 5 U.S.C. § 552(b); Inner City Press/Cnty. on the Move v. Bd. of Governors of the Fed. Reserve Sys., 463 F.3d 239, n.10 (2d Cir. 2006) (citation omitted). The Court is required to make specific findings as to segregability. Spadaro v. U.S. Customs & Border Prot., No. 16-CIV-16, 2019 WL 1368786, at \*7 (S.D.N.Y. Mar. 25, 2019) aff’d, 978 F.3d 34, n.2 (2d Cir. 2020) (quotation omitted). “Agencies are entitled to a presumption that they complied with the obligation to disclose reasonably segregable material.” Id. (quoting Sussman v. U.S. Marshals Serv., 494 F.3d 1106, 1117 (D.C. Cir. 2007)). Here, the Kotler Declaration proffers that personnel within the DFOI undertook a line-by-line review of the documents at issue and ensured that any non-exempt information that was reasonably segregable was disclosed. (Kotler Decl., at ¶ 25.) This is the type of affirmation that is entitled to the presumption of reliability and upon which courts often rely. See, e.g., Spadaro, 2019 WL 1368786, at \*7.

Plaintiff argues that documents that the FDA withheld in their entirety implicate the duty to segregate non-exempt material because the FDA did not address directly whether there is any non-exempt information in those documents. (Docket entry no. 74, at 19 n.10, 24 n.12) (citing entries 11-13, 34, 95, 100, 114-115, 117-118).) However, as mentioned above, the Kotler declaration includes affirmative statements that the documents were reviewed carefully and that all non-exempt, reasonably segregable information was disclosed. (Kotler Decl., at

¶ 25.) Plaintiff has not proffered evidence to the contrary and has not overcome the presumption of regularity that attaches to the FDA's proffer. Spadaro, 2019 WL 1368786, at \*7 (citing Sussman, 494 F.3d at 1117, for the proposition that the presumption must be overcome by "some 'quantum of evidence'" by the plaintiff); Sussman, 494 F.3d at 1117 (holding that some evidence of impropriety is required to overcome the presumption that an agency has complied with its duty to segregate material); Seife v. Food & Drug Administration ["Seife III"], 492 F. Supp. 3d 269, 281 (S.D.N.Y. 2020) (explaining Plaintiff had not "provided any other reason besides his own speculation for the Court to doubt Defendants' most recent redactions" and finding Vaughn index and affidavits sufficient). The presumption is further strengthened by the FDA's proffers, through the Vaughn index and Kotler and Rebello declarations, which are sufficient to demonstrate that each document is predecisional and deliberative. Accordingly, the Court finds that the FDA has met its burden of establishing that there is no non-protected information in entries 11-13, 34, 95, 100, 114-115, 117-118 that is reasonably segregable from the protected information in those documents, which are therefore properly withheld in their entirety.

### Foreseeable Harm

As amended by the FOIA Improvement Act of 2016 (the "FIA"), Pub. L. 114-185, 130 Stat. 538 (2016), 5 U.S.C. section 552 authorizes an agency to withhold information "only if . . . the agency reasonably foresees that disclosure would harm an interest protected by an exemption . . . or . . . disclosure is prohibited by law." 5 U.S.C.A. § 552(a)(8)(A)(i) (Westlaw Pub. L. 117-32). The FIA expressly provides that it "shall take effect on the date of enactment of this Act and shall apply to any request . . . made after the date of enactment of this Act." Pub. L. 114-185, 130 Stat. 538, 544-45 (2016). The FIA was enacted on June 30, 2016,

id., and Plaintiff submitted the Request on May 5, 2014. (Kotler Decl., at ¶ 13.) Nevertheless, Plaintiff argues that the FDA is required to show that harm to a protected interest would be a reasonably foreseeable result of disclosing the withheld records in this case. (Docket entry no. 83, at 8.) Plaintiff argues that, at the time of his request, federal agencies were required by to demonstrate foreseeable harm for withheld records as a matter of internal governmental policy, and that the FIA, which did not change the scope of information protected by exemptions, merely codified that pre-existing requirement. (Id. at 9.) Plaintiff's argument that the foreseeable harm requirement applies to pre-2016 FOIA requests is inconsistent with the plain language of the FIA and with persuasive decisions within this District holding that the FIA imposed "an independent and meaningful requirement" on agencies to justify withholding documents pursuant to FOIA exemptions. Natural Res. Def. Council, 2019 WL 4142725, at \*5; Nat'l Day Laborer, 486 F. Supp. 3d at 691; Seife III, 492 F. Supp. 3d at 277. Accordingly, the FIA's foreseeable harm standard is inapplicable to Plaintiff's FOIA request. The FDA has, in any event, met any applicable burden by proffering declarations identifying specific types of harm that would flow from the disclosure of the content of deliberations concerning non-final aspects of the messaging policy decisions for the announcement events that are in dispute here.

### **CONCLUSION**

For the foregoing reasons, Defendant's motion for summary judgment is denied as to the documents listed at entries 64-68 and 105 of the Vaughn index, and is otherwise granted as set forth above. Plaintiff's cross-motion for summary judgment is granted as to entries 64-68 and 105 of the Vaughn index, and is otherwise denied. Defendant is directed to produce the

documents corresponding to entries 64-68 and 105 of the Vaughn index within 14 days of the date of this Memorandum Opinion and Order.

The Clerk of Court is respectfully directed to enter judgment in accordance with this decision and close this case.

The Memorandum Opinion and Order resolves docket entry numbers 66 and 73.

SO ORDERED.

Dated: August 10, 2021  
New York, New York

/s/ Laura Taylor Swain  
LAURA TAYLOR SWAIN  
Chief United States District Judge